IRB ADVISOR

Your Practical Guide To Institutional Review Board Management

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IN THIS ISSUE

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The reporter and the IRB: Should IRBs get involved in investigative journalism?

Many debate whether IRBs should have role in journalism

As the debate continues over whether journalists in academic settings are subject to IRB oversight, a newspaper journalist has taken the unusual step of voluntarily seeking out IRB review of his work.

Douglas Fischer, a reporter for *The Oakland Tribune*, worked with a private IRB before embarking on a project to test the blood of a Berkeley, CA, family for environmental contaminants. Fischer says that prior to this experience, he had known about IRBs, but had never considered applying to one for review of a proposed story. But the complexity of his project — blood draws from a family of four, including two children — and a suggestion from a source led him to seek out the IRB.

He says now that the process, which added months to his project and cost his newspaper $1,300, was a positive one, and he'd use it again for a similar story.

"I feel like I've found religion here," Fischer says with a laugh.

"It's a cumbersome process, no question about it, and it would be impractical for everyday stories, but for large investigative pieces, I do see benefits," he says. "I think when there is a potential significant downside to the subjects, it's very helpful to have a board that is dedicated solely to protecting the well-being of the subjects to oversee things."

Fischer's goal was to find a family, have their blood drawn, and test the blood for a number of substances — flame retardants, PCBs, metals such as mercury and lead — that are found in residential environments. He says there has been little research on this subject, especially regarding children, and Fischer wanted to know to what extent regular household contact with cleaners, solvents, and other sources affected different members of the family.

He came up with a family willing to be studied, but at that point, he said, he was stymied by how to proceed. "I realized I was in totally over my head," he says. "I was going to be drawing blood from this family and sending it to a lab to be analyzed. I was going to get back numbers that could be scary. Something could go wrong when we were drawing

blood, plus with the child, I had no idea how much blood I could draw.

"The lab initially was telling me that they needed a lot of blood. I had no idea how much was safe to take out of an 18-month-old child that weighs 10 kilograms."

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• *Fax:* (800) 284-3291 • *E-mail:* stephen.vance@thomson.com
• *Address:* 3525 Piedmont Road, Building 6, Suite 400, Atlanta, GA 30305

Editors: **Suzanne Koziatek** and **Melinda Young**.
Vice President/Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@thomson.com).
Editorial Group Head: **Lee Landenberger**, (lee.landenberger@thomson.com).
Managing Editor: **Alison Allen**, (404) 262-5431, (alison.allen@thomson.com).

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Editorial Questions

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Seeking out an IRB

Fischer called **Greg Koski**, PhD, MD, former OHRP director and currently senior scientist at the Institute for Health Policy at Massachusetts General Hospital, Harvard Medical School in Boston.

Koski says that when he heard the details of Fischer's proposal, it sounded more like scientific research than simple reporting. "The more we talked about it, the clearer it became that this particular piece of [Fischer's project] was really a research study and in that manner no different than if I were doing it as a physician or a PhD were doing it in a biochemistry lab," he says. "I suggested that if he wanted to do this right, since there were privacy issues and a host of other issues that came up, that he should go through an IRB."

So Fischer went looking for a review board that would give him some guidance. IRBs at area universities turned him down because his employer was a for-profit company, but Independent Review Consulting (IRC), a Marin County, CA-based private IRB, was willing to accept his application.

Fischer filled out the same application form that any other investigator would, with help from a researcher he'd been working with on the project.

He devised a consent form that not only included information about the required blood draws but also the other aspects of his reporting on the stories.

"I'm rather proud of our consent form," he says. "It explained exactly what we were going to do in terms of the 'clinical trial' part — the testing, how much blood, what we would do with it, who would analyze it, what we would do with the samples afterward.

"Then it has another whole section on how the interviews would be conducted, that the photographer would be in their house taking pictures and it also explained that we would be publishing this in the newspaper and using photos and identifying features."

Under the terms of the informed consent, the family could withdraw from the project at any point up to publication, no questions asked, Fischer says.

One potential risk that Fischer outlined in the consent form was that because of the scarcity of research on this subject, the family could be upset by the information that the blood tests revealed.

"There was a potential for disturbing information — we told them that very clearly," he says.

"In talking with various doctors and researchers, I got the clear sense that I would give them numbers that we would not be able to interpret. And we put that in the description of risks and/or discomforts: 'You should be prepared for some uncertainty.'"

IRB review — of a sort

Erica Heath, MBA, CIP, president of IRC, says her IRB determined, in looking at Fischer's proposal, that it wasn't research in the strict sense of the term. The board wondered whether they could review it at all, and worried about being able to convey risks to a non-investigator.

"The activity proposed was a case study and was not research," she says. "There was question about whether it should be reviewed or if it should be considered to be not research or not regulated research. Once accepted for review, it was not as a 'study' and the usual review formula could not be used."

She says the risks to the family were seen to be similar to subjects in a bio-monitoring study.

Since Fischer's application was voluntary, she says the board gave him a sort of 'approval,' after counseling him to make changes that would minimize risks to the family. Among those changes, Fischer says, was providing a specialist for the family to consult after receiving results from the tests to answer their questions to the extent possible.

"It was one of the best suggestions that came from the IRB," he says. "They wanted me to find a doctor that specializes in these environmental contaminants and get the family in for whatever they needed after we got the results. And we did that, and it was great."

Another issue was harder to resolve. The board was particularly concerned about the effect of the testing on the children, noting that the information gleaned would follow them for life, and possibly hurt their ability to gain insurance in the future, Heath says.

In his revised proposal, Fischer argued that the information from the children was important. It could show, for example, whether the youngest child, who was breastfeeding, was receiving contaminants via the mother's breast milk. In addition, children's smaller bodies and proximity to the ground also make it more likely that they would have higher levels of contaminants in their blood.

Eventually, he says, he and the IRB worked out a minimal amount of blood to be drawn from the children that would meet his needs.

The resulting stories, published in March, revealed surprising details about the level of the family's exposure to contaminants, including the presence of unexpected levels of flame retardants in all four family members' blood samples.

Fischer says he hopes to do a follow-up story looking at blood tests from a number of mother-and-child pairs. If he goes forward with it, he said he definitely will seek out the services of an IRB again.

"I'm probably going to get totally vilified in journalism circles, but I think it would be helpful," he says. "This added three or four months to the project, not to mention going to my editor and saying we need another $1,300. But in the end, I think it's beneficial for everybody."

Heath, too, says she'd be willing to repeat the experience, not as an official IRB review, but as a public service to provide education about how research should protect human subjects.

She says one thing that made the process work was Fischer's openness about his project and what he was hoping to accomplish. "He recognized it was not research, he saw it for what it was," she says. "Therefore, we could work with him on an open, honest basis. That counts for a whole lot."

Koski says he was happy to learn that Fischer had actually gone through with the IRB review he had recommended, noting that many legitimate researchers complain about the process.

In an op-ed piece that accompanied the newspaper articles, he wrote: "In this case, Fischer and his editors clearly did the right thing, and their work was better for it. But, more importantly, their conduct demonstrated respect for the principles and practices that characterize responsibly conducted human research."

Fischer says after the work he did on this project, he doesn't understand the reluctance of bona fide researchers to having their work reviewed by IRBs. "I don't understand, if you're involving humans, why you wouldn't want to go through this process," he says. "I know it takes time, but I felt so much more comfortable once my protocol had been vetted — that I had these guys to kind of look over my shoulder and make sure this family is being adequately protected."

Journalistic disagreement

Neil Ralston, PhD, assistant professor of journalism at Northwestern State University in Natchitoches, LA, and a member of the board of directors and a campus adviser for the national

Society of Professional Journalists, says he sees no problem with what Fischer did.

"It was the reporter's choice," Ralston says. "It sounds like the reporter went out of his way to protect the people who took these tests and I think that would be a highly ethical thing to do."

But **Leon Dash**, a Pulitzer-Prize winning journalist and currently professor of journalism at the University of Illinois, Urbana-Champaign, IL, disagrees. "I think it's a big mistake," he says. "I would never do that. It's almost like dealing with issues of prior restraint, which the Supreme Court in the case of the Pentagon Papers found to be unconstitutional."

He says that the focus of IRBs and the focus of journalists are often in direct conflict — an IRB is concerned with protecting the subject, while a reporter is concerned with finding information from the subject, without necessarily putting the subject's needs first.

"The focus of journalism is in the public's interest, not in the interest of the people being interviewed," Dash says. "I think that's a major disconnect between IRBs and journalism."

Dash was a member of a University of Illinois panel that last year produced the Illinois White Paper, which contended that IRBs were engaging in "mission creep," delving into areas that were outside their purview rather than focusing on the research that needed their oversight most.

One example they used of IRB overreach was the suggestion that academic journalists — professors and students — might be required to submit their projects for IRB review.

"IRB purview leaves legitimate journalistic inquiry vulnerable to capricious decisions and creates confusion in the minds of students as to what is legitimately journalistic practice and what are the restraints of biomedical and even social science human subject research," the authors of the White Paper write. "Journalism is a clear example of a field that does not fit within the IRB review process."

Dash and Ralston says their institutions do not require IRB review of journalism projects. But at an another institution where Ralston taught, he learned that the IRB was considering a policy that would have required IRB approval for any research, including interviews, that were conducted by students.

"I went before the panel and told them that the First Amendment basically prohibited them from doing that, at least in terms of the journalism research," he says. "It was just prohibitive for my students to have to go to the IRB every time they wanted to do a story.

"The person who was in charge of it understood quickly and said, 'Yes, you're right, and we're not attempting to apply this to journalism students doing stories for publication.'"

Ralston does admit that there can be a gray line between what would be considered journalistic activity conducted by students or professors, and something that an IRB would consider research requiring review.

"It's quite possible where a journalist could conduct the same type of research that an academic might conduct, but the difference would be that the journalist would publish his or hers in a newspaper or broadcast outlet and the academic would publish his or hers in a journal," he says.

Excerpt from reporter's consent form

Here is an excerpt from Douglas Fischer's consent form for the family who participated in *The Oakland Tribune*'s series: "A Body's Burden: Our Chemical Legacy."

DESCRIPTION OF RISKS AND/OR DISCOMFORTS

"You may be concerned about the results (of the blood tests). The overwhelming body of evidence, particularly research done by the Centers for Disease Control and Prevention, suggests this study will find some amounts of all these chemicals in your bodies.

What we lack, however, is a suitable reference range to determine whether levels measured are high, low or average, though data from CDC and other studies will allow us to make some guesses. Furthermore, your doctor and those at (the University of California, San Francisco) clinics will not be able to explain why you have these chemicals in your body, where they came from, or what you can do to reduce exposure…

You should be prepared for some uncertainty, and (the newspaper) strongly recommends you meet with (a consultant chosen by the newspaper) at least once to discuss your results. (The consultant) is also available to talk with you prior to testing to discuss the risks, benefits and hazards of testing, and the newspaper invites you to do so."

For more details from the informed consent and the IRB application documents as well as Fischer's series, visit The Oakland Tribune's web site at: http://www.insidebayarea.com/ bodyburden. ■

"The IRBs, I'm sure, would have trouble with that. This is an issue that I think is going to have to be debated more."

But as far as Dash is concerned, there is no debate. He says that anything a journalist — privately employed by a newspaper, teaching at a university or a student in a class — does is journalism, and all are protected by the First Amendment from IRB intervention.

"I didn't give up my rights as a journalist because I agreed to go into a university setting and teach," he says.

Koski says he agrees that most journalism projects are not well-suited to review by an IRB. He says Fischer's project was unusual in that it required collecting specimens from people and essentially treating them as research subjects.

"The last thing in the world that we'd want to do is to have all journalists have their stories go before some kind of committee," he says. "That would be a scary thought.

"By and large, I would say that if a journalist actually does what would constitute a scientific study — whether it's social research or something like this, which was actually toxicological — that those would appropriately be subject to IRB reviews," he says. "But what would clearly constitute traditional journalistic practice, I would say no. Wouldn't want to go there. I think it would be a serious step down a slippery slope." ■

Fairness and common sense can ease tensions

PIs admit to deceit when IRBs are thought unjust

An anonymous survey of principal investigators (PIs) suggests that IRBs that are heavy-handed with research protocols might unwittingly encourage deceit among researchers.[1]

"Our goal was to keep the survey sanitized and anonymous, but we were surprised at the candor of replies that came back," says **Gerald Koocher**, PhD, dean of the school of health studies and professor of psychology at Simmons College in Boston.

The study concludes that IRB policies and treatment of investigators can impact PIs' behavior and morale. Koocher and co-investigator Patricia Keith-Spiegel used the Computer Retrieval of Information on Scientific Projects (CRISP) database of federally funded biomedical research projects conducted at universities, hospitals, and other research institutions to obtain names of PIs to survey.

CRISP is maintained by the Office of Extramural Research at the National Institutes of Health, includes projects funded by NIH, Substance Abuse and Mental Health Services, Health Resources and Services Administration, the FDA, CDC, Agency for Health Care Research and Quality, and Office of Assistant Secretary of Health.

The investigators surveyed PIs from the CRISP database and also sent questionnaires to psychologists found through the Association of Scientific Psychology, Koocher says.

"The questionnaire went out by mail, and we specifically asked people to not identify themselves and to just send us an e-mail message to receive a copy of the report," Koocher says. "We didn't want any identifying information on the questionnaires other than gender and age."

More than 1,000 questionnaires were sent out, and about 400-600 people replied. Some respondents called the researchers to offer narratives in response to the questions, Koocher says.

The narratives, published in *Ethics and Behavior*, offer striking examples of ethical and regulatory infractions. For example, one adapted scenario included in the published study described an investigator who felt mistreated by the IRB, so when his research protocol did not gain approval after two appeals, he submitted a paper for publication and reported the procedures as conforming to IRB mandates although he use used contrived data.[1]

In other examples, investigators loaded protocol descriptions with boring details and omitted controversial elements in order to gain smoother IRB approval, and another investigator routinely begins data collection before receiving IRB approval in response to frustrations over what she views as too-lengthy IRB reviews.[1]

Helping hand or conflict of interest?

While IRBs are not responsible for investigator malfeasance, they can address the perceptions of unfairness, which relates to the organizational justice theory, Koocher says. Koocher has spoken before audiences of investigators and IRB members or staff about the perceptions of PIs, and he's received some interesting feedback.

"One of the IRB administrators came up to me afterwards and said she felt such empathy for the desperation of some investigators," Koocher

recalls. "At her facility, there might be an investigator who has a large lab and is supporting dozens of people and he feels pressure that if funding isn't continued in a certain way then he will be forced to lay off people."

These human pressures, along with institutional pressures, can lead to unethical behavior, Koocher notes.

"In our experience, IRBs have fallen into three different categories, although obviously in a continuum," Koocher says. "At one end are the tight regulators, and their goal is to protect human subjects at all costs, which is fine, but the real purpose of the IRB was not to block research simply because one person might object to it."

Some IRB's are so risk averse in their approach to protocol reviews that they limit the amount of research that could be done, Koocher says.

"Some reasonable research is not done because of high barriers predicated on local standards," he explains.

"A the other end of the continuum are some lax IRBs that want more research at their institution," Koocher says. "Their attitude is, 'We know what we're doing, and we know everyone here,' and so maybe some studies slide through."

In the middle are the IRBs that Koocher and others might term an ideal IRB, which is one that assists researchers in doing what they want to do, but keeping the research consistent with the protection of human subjects, Koocher says. **(See suggestions for creating an ideal IRB, p. 91.)**

"So if you have a protocol that raises hackles about whether human subjects are adequately protected, the IRB should be in a position to help you tweak the study so it can rise to the level of acceptability and be done," Koocher says.

This is preferable to having an IRB simply create roadblocks, he adds.

"Some IRB administrators and members feel as though they are not allowed to help investigators, but it's not true," Koocher notes. "They have to have the integrity and protection of human subjects as their primary mission, but that's not to say they can't be helpful to investigators, especially if the research could be done ethically with some tweaking."

To IRB staff and members who say they can't help investigators because that would be a conflict of interest, Koocher responds, "You're job is to ensure good safe research, so why is helping them a conflict of interest?"

Another reason IRBs may not assist investigators in improving human subjects protection in their protocols is their institutions do not adequately staff the IRB, so they are too overwhelmed with the workload to provide extra help, Koocher adds.

So when IRBs create unnecessary barriers through misunderstanding or work overload, investigators may feel they are being unfairly treated and respond accordingly, Koocher says.

"There always are a few arrogant apples in the barrel, but most people get angry at an IRB that delays or doesn't seem responsive or which gives ambiguous feedback or raises objections without a clear basis for it," he explains.

Who's minding the store?

Another problem is the way IRBs are run, Koocher says. "In general, institutional review boards should vote on whether or not to approve a study," he says. "There are many places where an IRB chair or administrator decides they want to reach a consensus, and the problem with that approach is it allows one outspoken person to block a study."

The most outspoken person could be an ideologue who is misguided, and if that person holds sway then the result is like a criminal trial where there must be a unanimous decision, Koocher explains.

"You wouldn't want an IRB to pass something by a five-to-four vote, but by the same token, one strident voice shouldn't derail an otherwise acceptable protocol, especially if the strident voice comes from someone who doesn't have a strong knowledge of the study topic," he says.

With human subjects research review, the standard should be a preponderance of evidence, not a "beyond a reasonable doubt" standard, as used in the criminal justice system, Koocher adds.

This especially is true when research involves social-behavioral science and the worst risks are emotional, rather than physical, he suggests.

For instance, Koocher once was involved in a study about death and adolescents, and one of his questions was "Do you ever worry about dying?" This question had been standardized with normal adolescents, and he wanted to administer the test on adolescents who had serious illnesses, but only with their permission.

"One physician on the IRB said, 'You can't ask questions like that of kids,'" Koocher recalls. "But the test had been administered to hundreds of kids at other sites, and there were no ill effects reported."

Nonetheless, the doctor had a gut reaction to the study question, and his doubts caused other IRB members to question it too, Koocher says.

"We politely pointed out that this instrument had been used many years with no ill after-effects, so the IRB needed to consider whether there was significant evidence rather than an emotional reaction, and the IRB told us to go ahead with the study," Koocher concludes. ■

Reference:
1. Keith-Spiegel P, Koocher GP. The IRB paradox: could the protectors also encourage deceit? *Ethics & Behavior*. 2005:15(4):339-349.

How IRBs can improve investigators' opinion

IRBs should strive toward transparency

IRBs often err too much on the side of caution, creating a situation in which investigators do not trust their judgment and doubt their fairness, an expert says.

There are a number of ways an IRB can improve the review process, making it appear more equitable and reasonable to principal investigators, says **Gerald Koocher**, PhD, dean of the school of health studies and professor of psychology at Simmons College in Boston. Here are Koocher's suggestions:

1. Demonstrate consistency. "One thing IRBs could do is publish statistics every once and a while of how long the average protocol took to be reviewed and how many corrections were required," Koocher says.

Other statistics that would be helpful are:

— What percentage of protocols was declined?

— What were the most common mistakes needing corrections?

"Simple descriptive statistics in a report that principal investigators and others could read might be one example to attest to fairness," Koocher says.

2. Invite investigators to IRB meetings. "At one institution I was at, the IRB never invited investigators to be present," Koocher recalls. "At another IRB, investigators were asked to be available on call during the IRB meeting so if the IRB had questions, they could be invited in to answer them, and you can guess which IRB was seen as fair."

IRBs need to have a degree of transparency and to project a sense that all protocols are treated the same, whether they come from a chair of the department or a junior investigator, Koocher suggests.

3. Have a mechanism for corrections. It doesn't have to be an appeals process, but there should be some mechanism in which investigators can have the IRB's decision reviewed or reconsidered, Koocher says. This could be an informal challenge of the IRB's discussion about what are viewed as necessary changes to a protocol or consent form, Koocher says.

For example, Koocher once had a federal grant to create an intervention with families who had lost a child. The intervention would provide preventive psychotherapy to 120 families over a four-year period. When Koocher submitted the consent form, someone on the IRB sent a message back that it needed to be revised to tell participants about how investigators would be required to report any knowledge of child abuse according to the state's mandatory child abuse reporting laws.

"I challenged that," Koocher says. "If you have a family that has lost a child and has surviving children and you tell them that if they tell you they're abusing the surviving children that you'll call social services, then that's not helpful to them."

The statement itself could harm the participants, he adds. "I looked up statistics and saw that the probability of having a family that abuses children come into the study was less than one in 1,000, so with 120 families we wouldn't even expect it," Koocher says. "And if we did see child abuse, we'd stop the study and say that anything we saw would result in a report."

Finally, Koocher asked the IRB to consider whether every other study involving families that had been reviewed, including medical studies, was required to put in the child abuse reporting disclaimer.

"If they're asking me to do something risky, why aren't they asking everyone?" he says.

Finally, the IRB changed its decision and did not require the child abuse reporting phrase to be put in the informed consent. But without the opportunity to question the IRB's decision, Koocher would have been left with what he thought were only bad choices.

4. Make the IRB representative. IRB members should have knowledge in the research content areas of protocols they review, Koocher says.

IRB assessment tool

Researchers Patricia Keith-Spiegel and Gerald P. Koocher have developed an IRB assessment tool, which can be used by investigators to rate their ideal IRB and their own IRB. It also can be used as a self-assessment tool by IRB members and staff. Here is an excerpt from the tool, which can be found at www.ethicsresearch.com at the link to forms:

Please rate YOUR IRB on each item, as follows:
7 = Describes our IRB exceptionally well
6 = Describes our IRB very well
5 = Describes our IRB well
4 = Describes our IRB somewhat
3 = Only slightly describes our IRB
2 = Does not describe our IRB
1 = Definitely does not describe our IRB

(1) Our IRB is open to reversing its earlier decisions (i.e., willing to carefully listen to investigators' appeals).

(2) Our IRB has members who are very knowledgeable about IRB procedures and federal policy.

(3) Our IRB reviews protocols in a timely fashion.

(4) Our IRB's members do not allow personal bias to affect their evaluation of protocols.

(5) Our IRB applies appropriate flexible standards regarding voluntary and informed consent requirements (e.g., required wording is less demanding for minimal risk research using competent adult participants).

(6) Our IRB recognizes when it lacks sufficient expertise to evaluate a protocol and seeks an outside evaluator.

(7) Our IRB shows considerable evidence that the advancement of science is part of its mission.

(8) Our IRB is willing to work with investigators to find mutually satisfying solutions whenever disagreements exist.

(9) Our IRB offers editorial suggestions regarding consent documents and protocols (e.g., typos, grammar, clarity).

(10) Our IRB provides a comprehensive training program for its new members.

(11) Our IRB treats investigators with respect.

(12) Our IRB conducts a conscientious and complete review of protocols.

(13) Our IRB maintains complete and accurate records.

(14) Our IRB is open to innovative approaches to conducting research.

(15) Our IRB takes timely action when an investigator has violated the specifications of its rulings. ■

"One way IRBs can do that is to bring in ad hoc members," he suggests. "If you have an IRB composed of physicians and nurses and you receive a behavioral research study, it would be important to have a behavioral scientist to talk with about that study."

Likewise, an IRB that reviews protocols from a psychiatry department might need to have an endocrinologist expert as a consultant for when there are biomedical studies to review, Koocher adds.

"When the content area of the study is not represented in the expertise on the IRB, the board can enhance the sense of fairness by inviting in a consultant who has the necessary expertise," he explains.

"I don't know if that happens enough," Koocher notes. "I've been on IRBs where we've done that, such as one where we had a proposal about domestic violence of kids, and we had no one who knew about domestic violence, so we found an expert who could speak with us by speaker phone."

IRBs need to have a diverse nature and should represent members of the community and the range of specialties that are present at a research institution, Koocher says.

"This optimizes the likelihood that different viewpoints are represented," he says.

5. Work toward transparency: "IRBs can publish who is on the IRB, and they can describe what their procedures are," Koocher says. "They can publish minutes of the meeting without attribution."

This can be done without violating investigators' privacy or identifying exactly which IRB member made what comment, he adds.

Koocher was once involved with an IRB and when he asked who the members were, he was stonewalled. Finally, he informed the IRB that the members' names were public information, and were they going to make him file a Freedom of Information request.

For IRBs that would like to know how they perceive themselves and how investigators perceive them in the area of justice and fairness, there's a free, downloadable IRB assessment tool, which is available at the web site: www.ethicsresearch.com, Koocher says. **(See sample of assessment tool, left.)**

"Click on 'forms' at left and then scroll down to the IRB RAT rating assessment tool," Koocher says. "We're giving it away, and it's not copyrighted or anything we're trying to sell."

The instrument, which already is being used at many institutions, is likely to be a good tool for improving an IRB's image simply because it's rare for IRBs to ask investigators to tell them how they're doing, Koocher notes.

"One thing that was interesting is a lot of people who downloaded the instrument asked us to tell them how they compare," Koocher says. "We say we did not intend this to be used as a standardized instrument, and we don't want them to compare themselves with other institutions."

The goal is for IRBs to use this in their own institution, try it for a year, and then change what needs to be changed, and take the test again, he explains. ■

Listening, interactive media transform informed consent

Approach particularly helpful in complex trials

A new approach to informed consent currently being developed at St. Jude Children's Research Hospital could greatly improve the way in which patients and their families learn about complicated protocols, says the physician who is leading the development team.

The approach, which engages pediatric patients and their parents using an interactive media presentation on a handheld device, has great potential for use both inside and outside clinical research, says **Ray Barfield**, MD, PhD, a bone marrow transplant specialist at St. Jude in Memphis, TN.

Barfield says a team from St. Jude and the University of Memphis that includes health communications scholars, graphic artists and computer technicians has spent the last two years working on the project. They've used information gathered from physicians, other health care workers, patients, and families to try to overcome the vast learning challenge that awaits pediatric cancer patients and their families who are considering participating in a cancer trial.

"The most useful thing we've done is to begin with our foundational assumption, which is, we need to listen to the nurses, the physicians, the parents and patients to actually come up with interesting approaches to delivering information that's useful to them," Barfield says.

"I think just listening to people is a wonderful, generalizable lesson from this."

Frustration: The mother of invention

Barfield says his interest in this subject was borne out of frustration with trying to explain complicated protocols to patients and their families. He says his consent forms regularly run to 25 pages of single-spaced text.

"We struggle here with the process of informed consent, because the more complex the research protocols become, the more difficult it becomes to meet the goal of true informed consent," he says. "In an effort to include everything for the sake of completeness, there are times that we actually reach a point of diminishing returns, when the volume of information begins to become an obstacle to seeing what's most important about the research protocol."

Barfield describes the experience of trying to explain a protocol to a patient's family and seeing them having difficulty digesting the information.

"I would get 30 or 45 minutes into a discussion and feel that I was sort of losing people," he says. "It's like being a professor at the front of the class and you start to see all your students' eyes glaze over and you know the final exam is coming down the pike and you know they need to know it."

As he began to look at how he might approach informed consent from another perspective, he learned about a group from the University of Memphis' Center for the Study of Rhetoric and Applied Communications that wanted to find a way to work with St. Jude on health communications issues.

They enlisted the help of graphic artists from the university's Center for Multimedia Studies to find ways to overcome the information gap for patients and families.

An important step, Barfield says, was to set up the focus groups of physicians, health care workers, parents, and older St. Jude patients, ages 12-17.

Their input helped Barfield's team realize a few key points:

• Different people learn new information differently.

"This is a process of learning — the 'informed' part requires understanding, learning new terms, learning new ideas," he says. "Because the people who write the informed consent documents tend to be people who've been in school a lot, a text-based document is a natural approach to delivering information for us. But other people

respond to visual things, to graphic information, to verbal communication."

So the team explored the feasibility of developing a multimodal approach to delivering the informed consent information, so that everyone could review it in the way they understood best.

• Patients and families want to know what information is most important.

Barfield says one of the biggest complaints about the standard consent documents was that there was no prioritization of information.

"Everything is sort of presented the same," he says. "One consistent theme, especially from the parents and from the non-physician health care givers, is that it would be enormously helpful to stratify the information."

So the team worked to develop a hierarchy of information using a standard consent document as a model.

At the top level, would be the most important information about the protocol: "Absolutely crucial required information — if you don't get this, you don't understand the protocol," Barfield says.

Then, he says, there would be a second telling of the information in a more detailed way. Barfield describes it as a "recommended" section, for parents who want more depth.

Finally, for those who want to dig into the protocol even further, there would be access to PDF files of published articles about the subject that would be available through the St. Jude library.

"One of the nice things about this is it allows us to choose articles that are accessible, that are factually correct," he says. "That acts as a kind of antidote to the fire-hydrant approach to information that most people experience through the Internet."

Finding a successful model

When the team began to consider how they would relay this information to families, they looked at a successful model in another field: museums.

"We wanted an analogous situation, where you have an enormous amount of information, that is completely unfamiliar," he says. "We came up with the analogous situation of a museum, where you have room after room of unfamiliar information."

As they explored the idea further, they found a software company in Canada that specializes in working with museums. They teamed up with company to develop software that could run on a small handheld device — looking something like a personal digital assistant (PDA) — currently in use with museum exhibits.

For the first prototype, the team used one of Barfield's own protocols, breaking down the information and organizing it for use on the handheld device. In addition to text, the software employs graphic animations to help explain complicated processes.

"You can say, 'This is an antibody study, it's used to target neuroblastoma and it helps to focus the immune systems so that T-cells and natural killer cells can blah, blah, blah,' and nobody understands what you're talking about," he says. "With this animation, it's just beautiful, because you know what an antibody is and what it's intended to do."

As the team worked on this project, it became clear that this approach to informed consent was too resource intensive to use on every protocol, even at a large institution like St. Jude, which has an extensive protocol department. But Barfield does see the approach as having real value in a number of situations:

— Large, long-term studies involving many patients**.** Barfield says one example at St. Jude would be a large protocol for patients with acute lymphoblastic leukemia (ALL). "ALL is the most common pediatric malignancy and there's an enormous amount of institutional support for this protocol – it's the largest protocol we run," he says. "And it's the kind of protocol that you might be able to develop a module for that would have a five-year usefulness."

— Large national studies such as those conducted by the Children's Oncology Group (COG), where the consent program could be set up nationally and distributed, along with devices, to participating hospitals.

"If you have a children's hospital that's primarily taking care of kids rather than doing research, but they participate in COG studies, then they might benefit from having a COG protocol in this sort of format," Barfield says. "They could use the format, but they wouldn't have to develop it themselves because they're using a protocol from a national working group."

— Explanation of key concepts in research that cross protocols, such as the purpose of a Phase 1 trial or the idea of informed consent.

— Quality of life studies, in which the assent of the participating child is extremely important since he or she will be the one reporting the various measures of pain, depression or other factors.

— Informed consent for non-research procedures such as installing a central line. Because these procedures tend not to change much over time, the modules could be used for years, Barfield says.

Barfield says that as the team has continued to work on the project, they've found ways to more amend the software to make changes without heavy investments of time and resources.

"And the software is very, very flexible, so it's not attached to any one device," he says. "You could fit it onto any kind of hardware, including just a computer mainframe."

Barfield says usability testing for the device is being conducted this summer, to enable the team to revise it to make it even more usable and flexible for future research projects. ■

Register now for Duke OHRP conference

Registration is now open for the Office of Human Research Protections' national conference: "Crossing the Line: What is Acceptable Risk?" The event is scheduled for Sept. 25-26 in Durham, NC, and is sponsored by the Duke University School of Medicine.

Topics to be discussed include the use of deception in research with children, understanding risk and autonomy in overseas AIDS research and community recruitment of vulnerable groups. There also will be regulatory updates from representatives from OHRP, the FDA, NIH, and other federal agencies. For more information visit http://dukeohrp2006.org/. ▼

AAHRPP accredits its first international site

The Association for the Accreditation of Human Research Protection Programs Inc. (AAHRPP) of Washington, DC, now has awarded full accreditation to its first international organization, Samsung Medical Center in Seoul, Republic of Korea.

"Samsung Medical Center is a full-service hospital, and it has expertise in cancer treatment," says **Marjorie Speers**, PhD, AAHRPP executive director. "Samsung conducts clinical trials primarily, both for Korea and also for United States-sponsored research," Speers adds.

AAHRPP is working on accreditation with three other countries at present, and at the beginning of July there were a total of 39 organizations that had received accreditation. These organizations represented 106 hospitals and other entities, Speers says.

"Now, we're working with 380 additional organizations, so accreditation absolutely is something people want to do," Speers says. "Also, a number of sponsors of research are asking about accreditation — I think it has become a symbol of excellence and something that organizations want to achieve."

Over time, increasing numbers of international organizations will become accredited as they seek to attract U.S. sponsors, Speers predicts.

"I think there is significant incentive for foreign institutions to seek accreditation because they want to have a mechanism to demonstrate they can meet the U.S. regulations as well as their own countries' ethical codes," Speers says. "And just as it does for U.S. institutions, it will give them a competitive advantage."

The accreditation process begins with a self assessment, which typically take six to 12 months to complete. An application is submitted and a site visit is scheduled. The Council on Accreditation will make a determination regarding accreditation status, typically within three to six months of the site visit, Speers says. ■

COMING IN FUTURE MONTHS

- Ethnography and the IRB: Special challenges, controversial approaches
- Experts offer advice on best practices in staffing, office administration
- Research involving pregnant or childbearing age women remains controversial
- New device rules are explained

CE/CME Objectives

The CE/CME objectives for *IRB Advisor* are to help physicians and nurses be able to:

- **establish** clinical trial programs using accepted ethical principles for human subject protection;
- **apply** the mandated regulatory safeguards for patient recruitment, follow-up and reporting of findings for human subject research;
- **comply** with the necessary educational requirements regarding informed consent and human subject research.

Physicians and nurses participate in this medical education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue.

Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material.

After completing this activity at the end of each semester, you must complete the evaluation form provided and return it in the reply envelope provided to receive a credit letter. When your evaluation is received, a credit letter will be mailed to you.

CE/CME *questions*

5. The board that reviewed Douglas Fischer's proposal for testing a Berkeley family for environmental contaminants likened the project to what type of research study?
A. A Phase 1 trial
B. A psychological survey
C. A bio-monitoring study
D. None of the above

6. According to a study about researchers' attitudes toward IRBs, which of the following strategies could an IRB take to improve the way principal investigators view the board?
A. Demonstrate consistency by publishing statistics about protocol reviews
B. Invite investigators to IRB meetings
C. Work toward greater transparency about meetings and decisions
D. All of the above

7. Gerald Koocher, one of the authors of a study on principal investigator conduct and attitudes, suggests that IRBs should approve protocols based on what criteria:
A. beyond a reasonable doubt
B. preponderance of evidence
C. unanimous vote
D. none of the above

8. Focus groups interviewed by a St. Jude team reported that they would like to see more prioritization of information in informed consent documents.
A. True
B. False

Correction: The answer to question 3 in the July issue is C (Alabama and Nebraska).

Answers: 5. C; 6. D; 7. B; 8. A